



DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0945-0003-60D]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION]

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 264-0041

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier OS-0945-0003-60D and project title for reference, to Sherrette A. Funn, email: Sherrette.Funn@hhs.gov, or call (202) 264-0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: HIPAA Privacy, Security, and Breach Notification Rules, and Supporting Regulations Contained in 45 CFR parts 160 and 164.

Type of Collection: Extension

Abstract: Office for Civil Rights (OCR) requests approval to extend this existing, approved collection without changing any collection requirements. In 2021, OCR published a Notice of Proposed Rulemaking (NPRM) proposing modifications to the HIPAA Rules that would affect the hourly burdens associated with the HIPAA Rules. 86 FR 6446. OCR is reviewing public comment received on the NPRM about existing burdens associated with compliance with the HIPAA Rules, available at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202011-0945-001, and on changes in burden that could result from the modifications proposed in the NPRM. OCR will update this ICR to reflect the input we receive on this notice and through the rulemaking process.

Likely Respondents: HIPAA covered entities, business associates, individuals, and professional and trade associations of covered entities and business associates.

Annualized Burden Hour Table

Section	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average burden hours per Response [1]	Total Burden Hours
160.204	Process for Requesting Exception Determinations (states or persons)	1	1	16	16
164.308	Risk Analysis - Documentation [2]	1,700,000	1	10	17,000,000
164.308	Information System Activity Review – Documentation	1,700,000	12	0.75	15,300,000
164.308	Security Reminders – Periodic Updates	1,700,000	12	1	20,400,000
164.308	Security Incidents (other than breaches) – Documentation	1,700,000	52	5	442,000,000
164.308	Contingency Plan – Testing and Revision	1,700,000	1	8	13,600,000

164.308	Contingency Plan – Criticality Analysis	1,700,000	1	4	6,800,000
164.310	Maintenance Records	1,700,000	12	6	122,400,000
164.314	Security Incidents – Business Associate reporting of incidents (other than breach) to Covered Entities	1,000,000	12	20	240,000,000
164.316	Documentation – Review and Update[3]	1,700,000	1	6	10,200,000
164.404	Individual Notice—Written and E-mail Notice (drafting) [4]	58,482	1	0.5	29,241
164.404	Individual Notice—Written and E-mail Notice (preparing and documenting notification)	58,482	1	0.5	29,241
164.404	Individual Notice—Written and E-mail Notice (processing and sending) [5]	58,482	1,941	0.008	908,108
164.404	Individual Notice—Substitute Notice (posting or publishing) [6]	2,746	1	1	2,746
164.404	Individual Notice—Substitute Notice (staffing toll-free number) [7]	2,746	1	3.42	9,391
164.404	Individual Notice—Substitute Notice (individuals’ voluntary burden to call toll-free number for information) [8], [9]	113,264	1	0.125	14,158
164.406	Media Notice [10]	267	1	1.25	334
164.408	Notice to Secretary (notice for breaches affecting 500 or more individuals)	267	1	1.25	334
164.408	Notice to Secretary (notice for breaches affecting fewer than 500 individuals) [11]	58,215	1	1	58,215

164.410	Business Associate notice to Covered Entity - 500 or more individuals affected	20	1	50	1,000
164.410	Business Associate notice to Covered Entity - Less than 500 individuals affected	1,165	1	8	9,320
164.414	500 or More Affected Individuals (investigating and documenting breach)	267	1	50	13,350
164.414	Less than 500 Affected Individuals (investigating and documenting breach) -- affecting 10-499	2,479	1	8	19,832
164.414	Less than 500 Affected Individuals (investigating and documenting breach) -- affecting <10	55,736	1	4	222,944
164.504	Uses and Disclosures – Organizational Requirements	700,000	1	0.083333333	58,333
164.508	Uses and Disclosures for Which Individual authorization is required	700,000	1	1	700,000
164.512	Uses and Disclosures for Research Purposes [12]	113,524	1	0.083333333	9,460
164.520	Notice of Privacy Practices for Protected Health Information (health plans – periodic distribution of NPPs by paper mail) [13], [18]	100,000,000	1	0.004166667	416,667
164.520	Notice of Privacy Practices for Protected Health Information (health	100,000,000	1	0.002783333	278,333

	plans – periodic distribution of NPPs by electronic mail) [19]				
164.520	Notice of Privacy Practices for Protected Health Information (health care providers – dissemination and acknowledgement) [14]	613,000,000	1	0.05	30,650,000
164.522	Rights to Request Privacy Protection for Protected Health Information [15]	20,000	1	0.05	1,000
164.524	Access of Individuals to Protected Health Information (disclosures) [16]	200,000	1	0.05	10,000
164.526	Amendment of Protected Health Information (requests)	150,000	1	0.083333333	12,500
164.526	Amendment of Protected Health Information (denials)	50,000	1	0.083333333	4,167
164.528	Accounting for Disclosures of Protected Health Information [17]	5,000	1	0.05	250
	TOTAL		2,070		921,158,940

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer,

Office of the Secretary.